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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
10/225,361	05/16/00	MACK	D A-07860-3778

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EXAMINER

JOHANNSEN, D

ART UNIT	PAPER NUMBER
1655	8

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/525,361</b>	Applicant(s) <b>Mack et al</b>
	Examiner <b>Diana Johannsen</b>	Art Unit <b>1655</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Apr 11, 2001
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims 1-37 are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15)  Notice of References Cited (PTO-892)      18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_      20)  Other: \_\_\_\_\_

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**DETAILED ACTION**

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, drawn to methods of screening drug candidates, classified in class 435, subclasses 6 and 7.1.
  - II. Claim 4, drawn to methods of screening for agents that bind a protein, classified in class 435, subclass 7.1.
  - III. Claim 5, drawn to methods of screening for agents that modulate protein activity, classified in class 435, subclass 7.1.
  - IV. Claims 6-7, drawn to methods of evaluate the effect of a drug on a patient, classified in class 514, subclass 2.
  - V. Claim 8, drawn to a biochip, classified in class 435, subclass 287.2.
  - VI. Claim 9, drawn to methods of diagnosing cancer, classified in class 435, subclasses 6 and 7.23.
  - VII. Claims 10-14, drawn to antibodies, classified in class 530, subclass 387.1.
  - VIII. Claim 15, drawn to methods of screening for binding inhibitors, classified in class 435, subclass 7.1.
  - IX. Claims 16-21, drawn to methods of inhibiting cancer with antibodies, classified in class 514, subclass 2.

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- X. Claim 22, drawn to methods of inhibiting cancer with antisense nucleic acids, classified in class 514, subclass 44.
  - XI. Claims 23-24, drawn to peptides, classified in class 530, subclass 300.
  - XII. Claims 25-26, drawn to peptides, classified in class 530, subclass 300.
  - XIII. Claim 27, drawn to methods of eliciting an immune response with a protein, classified in class 514, subclass 2.
  - XIV. Claim 28, drawn to methods of eliciting an immune response with a nucleic acid, classified in class 514, subclass 44.
  - XV. Claim 29, drawn to proteins, classified in class 530, subclass 350.
  - XVI. Claim 30, drawn to nucleic acids, classified in class 536, subclass 23.1.
  - XVII. Claims 31-34, drawn to methods of treating cancer using an antibody, classified in class 514, subclass 2.
  - XVIII. Claim 35-36, drawn to methods of determining cancer prognosis, classified in class 435, subclass 7.1.
  - XIX. Claim 37, drawn to methods of neutralizing a protein, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions I, II, III, IV, VI, VIII, XIII, XVIII, and XIX are patentably distinct methods.  
While each of the methods may employ proteins, the methods are patentably distinct because they have different objectives and require different process steps. Invention I requires a step of adding

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a “drug candidate” to achieve the objective of screening drug candidates. Invention II requires a step of detecting binding between a protein and a “candidate bioactive agent” to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention IV requires a step of administering a drug to a patient to achieve the objective of evaluating drug effects. Invention VI requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention VIII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention XIII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XVIII requires a step of determining protein levels to achieve the objective of determining cancer prognosis. Invention XIX requires a step of contacting an agent with a protein to achieve the objective of neutralizing the protein.

Inventions I, II, III, IV, VI, VIII, IX, XIII, XVII, XVIII and XIX are patentably distinct methods. While each of the methods may employ antibodies, the methods are patentably distinct because they have different objectives and require different process steps. Invention I requires a step of adding a “drug candidate” to achieve the objective of screening drug candidates. Invention II requires a step of detecting binding between a protein and a “candidate bioactive agent” to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention IV requires a step of administering a drug to a patient to achieve the objective

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of evaluating drug effects. Invention VI requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention VIII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention IX requires a step of administering an antibody to a cell to achieve the objective of inhibiting cancer. Invention XIII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XVII requires a step of exposing tissue to an antibody or administering an antibody to an individual to achieve the objective of treatment. Invention XVIII requires a step of determining protein levels to achieve the objective of determining cancer prognosis. Invention XIX requires a step of contacting an agent with a protein to achieve the objective of neutralizing the protein.

Inventions I, IV, VI, X, and XIV are patentably distinct methods. While each of the methods may employ nucleic acids, the methods are patentably distinct because they have different objectives and require different process steps. Invention I requires a step of adding a “drug candidate” to achieve the objective of screening drug candidates. Invention IV requires a step of administering a drug to a patient to achieve the objective of evaluating drug effects. Invention VI requires a step of detecting gene expression to achieve the objective of diagnosing cancer. Invention X requires a step of administering antisense molecules to achieve the objective of inhibiting cancer. Invention XIV requires a step of administering nucleic acids encoding a protein or fragment thereof to achieve the objective of eliciting an immune response.

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Invention X is unrelated to Inventions II, III, VIII, IX, XIII, XVII, XVIII, and XIX.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods which require the use of different reagents, have different process steps and have distinct objectives. Invention X requires the use of nucleic acids, which nucleic acids are administered to a cell to achieve the objective of inhibiting cancer. Each of inventions II, III, VIII, IX, XIII, XVII, XVIII, and XIX require the use of proteins and/or antibodies. Invention II requires a step of detecting binding between a protein and a “candidate bioactive agent” to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention VIII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention IX requires a step of administering an antibody to a cell to achieve the objective of inhibiting cancer. Invention XIII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XVII requires a step of exposing tissue to an antibody or administering an antibody to an individual to achieve the objective of treatment. Invention XVIII requires a step of determining protein levels to achieve the objective of determining cancer prognosis. Invention XIX requires a step of contacting an agent with a protein to achieve the objective of neutralizing the protein.

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Invention XIV is unrelated to Inventions II, III, VIII, IX, XIII, XVII, XVIII, and XIX.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods which require the use of different reagents, have different process steps and have distinct objectives. Invention XIV requires the use of nucleic acids, which nucleic acids are administered to an individual to achieve the objective of eliciting an immune response. Each of inventions II, III, VIII, IX, XIII, XVII, XVIII, and XIX require the use of proteins and/or antibodies. Invention II requires a step of detecting binding between a protein and a “candidate bioactive agent” to achieve the objective of screening for binding. Invention III requires a step of detecting the effect of an agent on protein activity to achieve the objective of screening for modulated activity. Invention VIII requires a step of combining a protein, a candidate bioactive agent and an antibody to achieve the objective of screening for inhibition of binding. Invention IX requires a step of administering an antibody to a cell to achieve the objective of inhibiting cancer. Invention XIII requires a step of administering a protein to a patient to achieve the objective of eliciting an immune response. Invention XVII requires a step of exposing tissue to an antibody or administering an antibody to an individual to achieve the objective of treatment. Invention XVIII requires a step of determining protein levels to achieve the objective of determining cancer prognosis. Invention XIX requires a step of contacting an agent with a protein to achieve the objective of neutralizing the protein.

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Inventions V, VII, XI, XII, XV, and XVI are patentably distinct product because they are drawn to different products having different structures and functions. The nucleic acids encompassed by Inventions V and XVI are each composed of nucleotides linked by phosphodiester bonds. However, the biochip of group V is an array of nucleic acids in combination with other materials supporting and providing a particular structure to those nucleic acids, and said biochip is employed in methods such as screening. In contrast, the nucleic acids of Invention XVI lack these supporting materials and structure of the chip of Invention V, and function in "eliciting an immune response". The peptides, proteins and antibodies of Inventions VII, XI, XII, and XV are each composed of amino acids linked by peptide bonds. However, the peptides of Inventions XI and XII, while capable of eliciting an immune response, are incapable of performing the functional activities of the proteins of Invention XV, and do not require the presence of a pharmaceutical carrier. The antibodies of Invention VII are glycosylated, have a particular tertiary structure, and have particular binding properties which render them distinct from other peptides and protein. Further, the peptides of Invention XI and XII differ from each other in having different sequences (and therefore different structures) and different functional properties. Accordingly, Inventions V, VII, XI, XII, XV, and XVI are distinct from one another.

Inventions V and I, V and IV, and V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case, the biochip of Invention V may be used in a materially different process, such as methods of identifying novel homologues of CJA81.

Inventions VII and II-IV, VII and VI, VII and VIII-IX, and VII and XVII-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of invention VII may be used in a materially different process, such as methods of protein purification.

Inventions XI and VIII, XI and XIII, XI and XVII, and XI and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides of Invention XI may be used in a materially different process, such as methods of screening for peptide activity or effects in an organism.

Inventions XII and VIII, XII and XIII, XII and XVII, and XII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

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different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides of Invention XII may be used in a materially different process, such as methods of screening for peptide activity or effects in an organism.

Inventions XV and I-IV, XV and VI, XV and VIII, XV and XIII, XV and XVIII-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Invention XV may be used in a materially different process, such as methods of protein purification.

Inventions XVI and X and XVI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Invention XVI may be used in a materially different process, such as methods of detection by hybridization.

Inventions V and II-III, V and VIII-X, V and XIII-XIV, and V and XVII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the biochip of Invention V is not

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disclosed as capable of use in the methods of Inventions II-III, VIII-X, XIII-XIV, and XVII-XIX, and function in methods that are materially distinct and have different effects from those of Inventions II-III, VIII-X, XIII-XIV, and XVII-XIX, such as, e.g., methods of screening for novel gene homologues.

Inventions VII and X and VII and XIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of Invention VII are not disclosed as capable of use in the methods of Inventions X and XIII-XIV, and function in methods that are materially distinct and have different effects from those of Inventions X and XIII-XIV, such as, e.g., methods of protein purification.

Inventions XI and I-IV, XI and VI, XI and IX-X, XI and XIV, and XI and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the peptides of Invention XI are not disclosed as capable of use in the methods of Inventions I-IV, VI, IX-X, XIV, and XVIII, and function in methods that are materially distinct and have different effects from those of Inventions I-IV, VI, IX-X, XIV, and XVIII, such as, e.g., methods of screening for peptide activity or effects in an organism.

Inventions XII and I-IV, XII and VI, and XII and IX-X, XII and XIV, and XII and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of

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use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the peptides of Invention XII are not disclosed as capable of use in the methods of Inventions I-IV, VI, IX-X, XIV, and XVIII, and function in methods that are materially distinct and have different effects from those of Inventions I-IV, VI, IX-X, XIV, and XVIII, such as, e.g., methods of screening for peptide activity or effects in an organism.

Inventions XV and IX-X, XV and XIV, and XV and XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein composition of Invention XV is not disclosed as capable of use in the methods of Inventions IX-X, XIV, and XVII, and function in methods that are materially distinct and have different effects from those of Inventions IX-X, XIV, and XVII, such as, e.g., methods of eliciting an immune response employing a protein.

Inventions XVI and I-IV, XVI and VI, XVI and VIII-IX, XVI and XIII, and XVI and XVII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acids of Invention XVI are not disclosed as capable of use in the methods of Inventions I-IV, VI, VIII-IX, XIII, and XVII-XIX, and function in methods that are materially distinct and have different

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effects from those of Inventions I-IV, VI, VIII-IX, XIII, and XVII-XIX, such as, e.g., methods of eliciting an immune response employing a nucleic acid.

3. If applicant elects either Group I or Group VIII, applicant is required to further elect a single patentably distinct gene or protein. **This is not an election of species.** By statute, “[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.” 35 U.S.C. 121. Pursuant to this statute, the rules provide that “[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claim shall be restricted.” 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Inventions I and VIII encompass the use of multiple distinct nucleic acids/proteins which are structurally distinct chemical compounds and are unrelated to one another. These molecules and methods requiring their use are deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid or protein is presumed to represent an independent and distinct invention, subject to restriction pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Should applicant traverse on the grounds that the different species encompassed by Inventions I and VIII are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

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over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-XIX require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the

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Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

July 2, 2001

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER